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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,426	09/27/2001	Marcus C. Merriman	47097-01106USC1	4436
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JENKENS & GILCHRIST, P.C. 225 WEST WASHINGTON SUITE 2600 CHICAGO, IL 60606			EXAMINER MADSEN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1761	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,426

Applicant(s)

MERRIMAN ET AL.

Examiner

Robert Madsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004 and 15 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-56 and 76-168 is/are pending in the application.
- 4a) Of the above claim(s) 87-118, 122, 141 and 160 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-56, 76-86, 119-121, 123-140, 142-159 and 161-168 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/27/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The Amendment file October 18, 2004 and the Letter filed November 15, 2004 have been entered into the file. Claims 38-56 and 76-168 remain pending, with claims 87-118, 122, 141, and 160 being withdrawn from further consideration as being directed to a non-elected species.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 38, 40-56, 76, 78-86, 119, 121, 123-138, 140, 142-157, 159, 161-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockley III et al. (US 5686127) in view of Koch et al. (US 3459117) and Woodruff et al. (US 4522835) and Shaklai (US 6042859).

4. Stockley et al. teach supplying a first polystyrene foam tray as recited in claims 41, 51, 79, 84, 123, 132, 142, 151, 161, 166 placing a retail meat in the tray, preferably removing oxygen to less than 0.5%, or even less than 0.05% (or less than 500 ppm, as recited in claims 44, 45, 81, 82, 125, 126, 144, 145, 163, 164), to inhibit or prevent the formation of metmyoglobin by gas flushing with carbon dioxide and/or nitrogen as recited in claims 47, 48, 50, 128, 129, 147, 148, or alternatively removing oxygen by vacuum as recited in claims 46, 127, 146, sealing

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the tray with a first oxygen permeable layer polyolefin overwrap as recited in claims 52,133,152,157, sealing a second oxygen impermeable layer to the first layer wherein the second layer is peelably removable from the first layer, as recited in claims 40,78,121,140,159, and removing the second layer without removing the first as recited in claims 38,76,157, to expose the meat to oxygen so that the meat is red in color for retail display, as recited in claim 42, 119,138 (Column 1, lines 1-62, Column 5, lines 2-8, 32-36, Column 7, lines 8-30, Column 8, lines 23-64).

5. Stockley et al. are silent in teaching in teaching 0.1-0.8%,0.3-0.5% , or 0.1-0.5%, carbon monoxide in addition to the carbon dioxide and nitrogen or just carbon dioxide to form carboxymyoglobin, as recited in claims 38,50,55,56,76,85,86,119, 131,136, 137, 138, 150,155,156,157,167,168, using an oxygen scavenger as recited in claims 43,80,124,143,162, converting deoxymyoglobin directly to carboxymyoglobin as recited in claim 54,135,154 or oxymyoglobin to carboxymyoglobin as recited in claim 53,134,153, the particular level of carbon dioxide and nitrogen in combination as recited in claims 49, 83, 131,149, 165, and wherein the carbon monoxide is associated with the raw meat is adapted to be removable after the second layer is removed, as recited in claims 38,76,119,138, and157.

6. Koch et al. are also concerned with providing a red-colored meat at the retail outlet. Koch et al. teach a bright red color is needed to make meat attractive for sale. However, Koch et al. teach maintaining the red color at the retail outlet for a longer time period by contacting the surface of the meat with

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carbon monoxide (CO). Koch et al. teach wrapping a meat with CO containing film under a modified atmosphere, whereby the CO is transferred from the film to contact the surface of the meat so that carboxymyoglobin is formed on the meat surface (Column 1, lines 23-50, Column 2, line 67 to Column 3, line 3, Column 3, line 49 to column 4, line 10). Koch et al. teach the meat will remain a "saleable" red color for as long as 10 days when the modified atmosphere package remains in contact with the meat for 7 days, and the modified atmosphere CO-containing package is removed from contact with the meat for 3 days (replaced by a conventional wrapper) at the retail outlet (Column 3, lines 4-16). Thus, Koch et al. teach that CO is removably associated with a meat surface since the color is "fixed" for only a finite time after the CO-containing wrapper is removed.

7. Woodruff et al. also teach meat that is stored in a refrigerated or frozen state under low oxygen conditions prior to final sale/consumption packaging. Woodruff et al. teach removing the O₂ causes the meat to turn purple, but by including carbon monoxide in the package a desirable red color, or the same color as fresh meat, is provided during storage. Woodruff et al. further teach only the first 0.25 inch of the meat are actually affected by the CO. Woodruff et al. teach treating storing meat in a reduced oxygen modified atmosphere of 0.1-3% CO, with at least 10% CO₂, or preferably 20-60% CO₂, 40-80% N₂, and 0% O₂ and convert deoxymyoglobin to carboxymyoglobin on the surface of the meat, wherein the O₂ is removed by evacuation or flushing, as taught by Stockley et al., and further alternatively using a scavenger for a sufficient time period to remove the oxygen (Abstract, Column 1, line 63 to Column 3, line 30, Examples). Thus,

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whereas Koch et al. teach film containing CO for turning the surface of a meat red, Woodruff et al. teach a gaseous mixture with CO for turning the surface, or to a depth of 0.25 inch, of a meat red.

8. Shaklai also teaches storing meat utilizing CO, albeit in a 100% CO environment. Shaklai teaches the entire meat becomes red, but after removing the meat from the CO enriched environment and exposing the meat to room atmosphere the outer 1mm eventually becomes brown in 14 days. Thus, Shaklai teach that upon exposure to air CO is removable from at least the first 1 mm of the surface after 14 days (Example 4 in light of Example 3 in Column 9).

9. Therefore, it would have been obvious to modify the carbon dioxide/nitrogen atmosphere taught by Stockley et al. and include anywhere from 0.1-0.8% carbon monoxide as recited in claims 38,50,55,56,76,85,86,119, 131,136, 137, 138, 150,155,156,157,167,168, since Koch et al. teach it is desirable to expose the surface of a meat to CO during modified atmosphere storage so that the meat surface will turn red and remain a saleable red color for an extended but finite time when the meat is exposed to room atmosphere at the retail outlet and Woodruff et al. how to expose the surface of a meat to CO during modified atmosphere storage so that the meat surface (i.e. down to 0.25 inch) will turn red: including 0.1-0.8% CO in the modified atmosphere gas composition. Furthermore, one would expect that modified Stockley et al. (i.e. with the 0.1-0.8% CO of Woodruff et al.) would result in a package wherein the carbon monoxide being adapted to be removable from the meat when the second layer is removed, or when the meat is exposed to room air, as recited in

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claims 38,76,119,138, and 157, since Koch et al. teach CO treated meat will only remain red for a finite time after being exposed to normal room air (e.g. 3 days if the surface is exposed to CO for 7 days), Woodruff et al. teach that 0.1-0.8% CO only affects 0.25 inch from the surface of the meat, and Shaklai teach even CO-saturated meat will lose its red color to the depth taught by Woodruff et al. (i.e. 0.25 inch) within 14 days of exposure to room air .

10. It would have been further obvious to modify the carbon dioxide/nitrogen mix taught by Stockley et al. and select 40-80% nitrogen, and 20-60% carbon dioxide as recited in claims 49, 83, 131,149, 165 since Woodruff et al. teach 0.1-0.8% carbon monoxide in combination with a at 40-80% nitrogen/ 20-60% carbon dioxide blend will provide the desirable red color of fresh meat for meat stored within a low/no oxygen modified atmosphere. It would have been further obvious to modify Stockley et al. and use an oxygen scavenger as recited in claims 43,80,124,143,162, depending on the time allotted to the manufacture to achieve a low oxygen environment since Woodruff et al. teach that obtaining a low oxygen environment may be achieved by a variety of ways such as evacuation and flushing as taught by Stockley, or alternatively with the addition of an oxygen scavenger wherein *sufficient* time is required to deplete the oxygen level. With respect to forming carboxymyoglobin from deoxymyoglobin or oxymyoglobin, as recited in claims 53,54,134,135,153, and 154, forming the carboxymyoglobin from either would have depended on the level of oxygen remaining in the modified atmosphere after flushing since Stockley III et al. teach

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such packages may contain anywhere from less than 0.5% to less than 0.05% oxygen.

11. Claims 39, 77, 120, 139, 158, are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockley III et al. (US 5686127) in view of Koch et al. (US 3459117) and Woodruff et al. (US 4522835) and Shaklai (US 6042859) as applied to claims 38, 40-56, 76, 78-86, 119, 121, 123-138, 140, 142-157, 159, 161-168 above, further in view of Garwood (US 5629060).

12. Stockley et al. teach an oxygen impermeable second layer peelably adhered to an oxygen permeable first layer covering a meat tray under a modified atmosphere wherein removal of the second layer will result in exposing the meat to atmospheric oxygen, but are silent in teaching a pocket is formed between the two layers.

13. Garwood also teaches an oxygen impermeable second layer peelably adhered to an oxygen permeable first layer covering a meat tray under a modified atmosphere wherein removal of the second layer will result in exposing the meat to atmospheric oxygen. However, Garwood teaches that quite often the first layer is ruptured during the peeling of the second layer, and teaches forming a pocket between the two layers, via a rigid second layer a seal strip between the two layers, will minimize contact between the two layers and prevent the chance of rupturing the first layer while removing the second (Column 1, line 14 to Column 2, line 56, Column 2, line 49-65, Column 5, line 35 to Column 6, line 11). Therefore, it would have been obvious to modify the second layer of

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Stockley et al. such that a pocket is formed between the first and second layer since Garwood teaches this will prevent rupturing the first layer during the peeling/removal of the second layer when exposing the meat in the tray to the atmosphere.

Response to Amendment

14. The Declaration under 37 CFR 1.132 filed October 18, 2004 by Dr. Melvin C. Hunt and the Declaration under 37 CFR 1.132 filed October 18, 2004 by Mr. Gary DelDuca are insufficient to overcome the rejection of claims overcome the rejection of claims 38-56, 76-86, 119-121, 123-140, 142-159, and 161-168 based upon as set forth in the present Office action because: The Declarations state the prior art considered CO to "fix" the color. However, the prior art of record currently applied in the rejection of the pending claims not only teaches that meat turns red, or carboxymyoglobin is formed, in the presence of CO, but that CO is removably associated, at least to a depth of 1mm. As stated in the rejections above, Shaklai teaches meat that is completely saturated with CO does not have a fixed color. In fact, after exposing CO to air for 14 days the surface (or <1mm deep) of the meat turns brown. Koch et al. teach only exposing the surface of a meat to CO to provide a red color by encasing the meat in a CO-containing wrapper. Koch et al. teach the red color is maintained for 10 days: 7 days in contact with CO-containing wrapper, followed by 3 days without contact with CO. Thus, Shaklai and Koch et al. teach the meat surface will turn brown within days after being exposed to a normal atmosphere, regardless of the level of CO the

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meat is exposed to during storage (i.e. mere surface exposure or 100% saturation). One would expect that at the levels taught by Woodruff, 0.1-3% CO, and the depth of CO saturation taught by Woodruff, 0.25 in (i.e. less than 1mm), that the CO would be removable from surface, since even a CO saturated piece of meat will lose its red color at the surface after 14 days exposure to room air. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Arguments

15. Applicant's arguments filed October 18, 2004 with respect to the rejections have been fully considered but they are not persuasive.

16. Applicant argues that the present invention does not "fix" the color, and that it is believed that the meat would turn brown in a natural time period.

Applicant notes that there is no suggestion to combine the references because none of the references teach new limitation of the carbon monoxide being associated with the meat is *adapted to be removable* when the meat is exposed to the room atmosphere.

17. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally

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available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Koch et al. provide motivation for allowing CO to contact a meat surface while the meat is stored in a modified atmosphere package: to extend the red color of the meat at the retail outlet when the meat is exposed to room atmosphere. Woodruff et al. teach how much CO is required (i.e. using 0.1-3% CO) in a modified atmosphere to create a red color meat surface (i.e. for a depth of 1 mm). Additionally, the prior art (e.g. Koch et al. and Shaklai) teaches that CO “fixes” the color of the *surface* layer of the meat for only a finite number of days. Koch et al. teach a meat surface contacted with CO for 7 days will only remain fixed in color for 3 days after exposure to room atmosphere, and even when the meat has been 100% saturated with CO, Shaklai teaches the surface layer (e.g. a depth 1mm) reverts back to a brown color within 14 days after being exposed to room atmosphere. Thus, the prior art recognizes that the number of days the surface of the remains red depends on the level of CO to which the meat is exposed. Furthermore, one would expect that a modified atmosphere like the one taught by Woodruff et al., which only affects the first 1 mm of meat, would provide a red surface color for anywhere from 3-14 days in light of Koch et al. and Shaklai when the meat is exposed to room atmosphere.

18. Applicant further argues that Applicant is the first to have FDA approved CO-containing meat packages, as noted above the art recognized storing meat in a modified atmosphere package wherein the meat surface is exposed to CO and

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the CO is removable from the surface of the meat once the modified atmosphere is removed. Considering the prior art as whole, the fact that FDA had not approved the use of CO is not relevant to the issue of obviousness in this case. Patent law is independent from FDA regulatory law. This issue often is discussed with respect to the determination of pharmaceutical utility (MPEP 2107.01: Section V.) :

“FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws.” *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir.1994)).

19. With respect to the present invention meeting a long-felt need, establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967). It is notoriously well known in the art, as discussed in the various references cited, that a red colored meat at the retail outlet is most desired. The prior art also recognizes that it is desirable to extend the time period that the meat exhibits a red-color. *Koch et al.* and *Shaklai* in particular teach meat exposed to CO in a modified atmosphere environment will provide the meat with a red color after the meat is removed from the modified

atmosphere environment for an extended period time, as compared to non-treated meat.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

21. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Madsen whose telephone number is (571) 272-1402. The examiner can normally be reached on 7:00AM-3:30PM M-F.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax


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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Madsen 
Examiner
Art Unit 1761

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